

**REMARKS**

Claims 1, 10, 42, 58-59, 62, and 68-93 have been amended, claim 8 has been canceled without prejudice or disclaimer. Thus, the pending claims are 1, 10, 42, 58-59, 62, and 68-93.

**I. Formal Matters**

The Examiner objects to the title and abstract of the application as not being descriptive of the claimed invention. Applicants respectfully submit that the title and abstract, as amended herein, are clearly indicative of the invention to which the elected claims are drawn. Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

The Examiner has asserted that the first paragraph of the specification is incomplete. Particularly the Examiner asserts that Parent Application 08/996,685 is a continuation in part of US Application 08/761,543, filed 6 December 1996, now US Patent 5,780,489, a continuation-in-part of US Application 08/875,015 and a continuation-in-part of PCT/EP96/02672. Additionally, the Examiner asserts that the declaration indicates that the instant application claims benefit of US Application 08/981,575 and of PCT/EP96/00096. Applicants respectfully draw the Examiner's attention to the paper entitled "Deletion of Priority Claims" dated December 12, 2001, a copy of which is enclosed, submitted when the instant application was filed. Said paper requested deletion of domestic priority claims under 35 U.S.C. § 120 of United States Application Nos. 08/761,543, filed December 6, 1996; 08/875,015, filed July 16, 1997; and 08/981,575, filed December 22, 1997, and under 35 U.S.C. § 365(c) of PCT International applications designating the United States, PCT/EP96/00096, and PCT/EP96/02672. Thus, Applicants submit that these priority claims should not be recited in the first paragraph of the specification as indicted by the Examiner. Therefore, Applicants respectfully request that this objection be withdrawn.

The disclosure has been objected to because it included a Table of Contents on pages i-v. Applicants have deleted pages i-v.

## **II. Claim objections**

Claims 8, 10, 42, 58-59, 62 and 68-93 have been objected to for having an improper article at the start of the claims. Claims 10, 42, 58-59, 62, and 68-93 have been amended to start with the proper article. Claim 8 has been cancelled making the objection to this claim moot.

In claim 42, the phrase “following group” was objected to. This phrase has been replaced with the phrase “group consisting of” as suggested by the Examiner.

In claim 93, the placement of the colon was objected to. The colon has been deleted as suggested by the Examiner.

## **III. Rejections under 35 U.S.C. § 112, ¶ 1:**

### *Written Description*

The Examiner rejected Claim 93 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. (Office Action at page 3.) Particularly, the Examiner asserts that the phrase “wherein the plant is ... chili” is not supported by the specification nor originally filed claims. Applicants have deleted the term “chili” from claim 93, thus obviating this rejection.

Claim 1, and dependent claims 42, 58-59, 62 and 68-93 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. (Office Action at page 7.) In particular, the Examiner contends that the specification does not describe, within the full scope of the claims, DNA molecules that hybridize to SEQ ID NO: 6, wherein the nucleic acid

encodes a protein involved in the signal transduction cascade leading to systemic acquired resistance in plants.

Amended claim 1 is drawn to a method of conferring fungal resistance on a plant. Said method involves first identifying a nucleotide sequence that encodes a plant immunomodulating protein, wherein the protein is capable of conferring synergistic fungal resistance when used in combination with one of the microbiocides selected from the group consisting of : (RS)-N-(2,6-dimethylphenyl-N-(methoxyacetyl)-alanine methyl ester ("metalaxyl", "ridomil"), ethyl hydrogen phosphonate ("fosetyl"), copper hydroxide or BTH, and wherein the complement of the nucleotide sequence hybridizes to the nucleotide sequence set forth in SEQ ID NO: 6 under the recited hybridization and wash conditions.

Applicants respectfully submit that according to the revised guidelines concerning compliance with the written description requirement of 35 U.S.C. § 112, first paragraph, it may be shown that "an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, *or some combination of such characteristics*" (see MPEP 2163, pp. 2100-165 to 2100-166 (emphasis added)). Thus, adequate written description can be provided by some combination of complete or partial structure, other physical and/or chemical properties, or functional characteristics when coupled with a known or disclosed correlation between function and structure.

Applicants submit that claim 1 and the claims dependent therefrom comply with the written description requirement. The features that distinguish the nucleotide sequences of part (a) of claim 1 from other nucleotide sequences are both structural and functional because: (1) they encode proteins that, when expressed in transgenic plants, give rise to immunomodulated plants with a constitutive immunity phenotype, as described throughout the specification, particularly at page 77, lines 17-19, and that must be able to confer a synergistic fungal resistance when used in

combination with certain fungicides ; and (2) they must hybridize to SEQ ID NO: 6 under the recited hybridization and wash conditions.

Furthermore, in support of this rejection, the Examiner has cited the *UC v. Eli Lilly* case (43 USPQ2d 1398 (Fed. Cir. 1997)), which is discussed extensively in the PTO Interim Guidelines on Written Description, pertained to claims directed to cloned genes themselves, not claims to processes that involve the use of cloned genes, which is the case with the instant invention. In fact, the PTO Interim Guidelines on Written Description were characterized by the Office as being “intended primarily for product claims rather than process or product-by-process claims” (PTCJ, vol. 56, no. 1381). Thus, Applicants respectfully submit that the *UC v. Eli Lilly* case should not be applied in a rejection of the pending method claims.

Finally, Applicants note that this rejection is moot with respect to claim 8 since the claim has been cancelled.

For the reasons set forth above, Applicants submit that the instant application provides sufficient written description for the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

### *Enablement*

Claim 1, and dependent claims 42, 58-59, 62 and 68-93 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification to enable one skilled in the art to make and/or use the invention. The Examiner contends that the specification does not reasonably provide enablement for a method of protecting plants from pathogen attack by applying a microbiocide to a plant transformed with a nucleic acid that hybridizes to SEQ ID NO: 6.

Amended claim 1 is drawn to a method of conferring fungal resistance on a plant. Said method involves first identifying a nucleotide sequence that encodes a plant immunomodulating protein, wherein the protein is capable of conferring synergistic fungal resistance when used in

combination with one of the microbiocides selected from the group consisting of : (RS)-N-(2,6-dimethylphenyl-N-(methoxyacetyl)-alanine methyl ester (“metalaxyl”, “ridomil”), ethyl hydrogen phosphonate (“fosetyl”), copper hydroxide or BTH, and wherein the complement of the nucleotide sequence hybridizes to the nucleotide sequence set forth in SEQ ID NO: 6 under the recited hybridization and wash conditions.

The Action states that the specification does not support the broad scope of the claims because it does not provide guidance for (a) the sequence of any nucleic acid that hybridizes to SEQ ID NO: 6, (b) for which amino acids of SEQ ID NO: 2 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain signal transduction activity of the encoded protein. The Action concludes that because of the unpredictability of the art and lack of guidance in the specification, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that hybridize to SEQ ID NO: 6.

Applicants respectfully submit that the requirement described in point b is not required by the statute, and Applicants are not aware of case law that includes such requirements. The standard for determining if a specification meets the enablement requirement is whether the experimentation needed to practice the invention is undue or unreasonable, and “even though the statute does not use the term ‘undue experimentation’, it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation” (MPEP 2164.01, emphasis added). Knowledge of which regions of the protein may or may not be changed is not necessary when identifying which proteins are capable of giving rise to immunomodulated plants and capable of synergistic interaction with certain fungicides. The specification provides ample direction and guidance for the skilled person to identify nucleotide sequences that encode such proteins and that hybridize to SEQ ID NO: 6. The specification gives further guidance as to how to determine whether a protein is immunomodulating and whether the protein is capable of synergistically interacting with the recited fungicides.

It is respectfully submitted that the present invention can be practiced without undue experimentation. Enablement of a disclosure “is not precluded by the necessity for some experimentation such as routine screening.” In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The experimentation necessary must not be undue. Id. At 737. Undue experimentation is experimentation that would require a level of ingenuity beyond what is expected from one of ordinary skill in the field. Fields v. Conover, 170 USPQ 276, 279 (CCPA 1971). Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims (In re Wands).

The present specification provides guidance to the skilled person regarding isolation of DNA sequences that encode plant immunomodulating proteins (Example 32), a description of important properties of these proteins (Example 23 and page 77), transforming plants with said DNA sequences (Example 20), determining whether the transgenic plant is immunomodulated and gives rise to a constitutive immunity phenotype (Example 22, Example 31) and testing for synergistic interaction with certain microbicides (Example 34). It is respectfully submitted that upon reading Applicants’ detailed specification the skilled worker would be able to carry out the present invention commensurate with the scope of the claims.

In light of the amendments to the claims and the above remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 1 and the claims dependent therefrom under 35 U.S.C. § 112, first paragraph.

#### **IV. Rejections under 35 U.S.C. § 112, ¶ 2:**

Claim 1 and dependent claims 8, 10, 42, 58-59, 62, and 68-93 were rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite for failing to particularly point out

and distinctly claim the subject matter that Applicants regard as the invention. Particularly, claim 1 was alleged to be indefinite in its recitation of the phrase “involved in the signal transduction cascade leading to systemic acquired resistance.” Amended claim 1 has deleted this phrase thus obviating the rejection.

Claim 1 was alleged to be indefinite for recitation of the terms “(X3)” and “(X1)”, and for the phrase “at 55°C.” Claim 1 has been amended to make the recited hybridization conditions more clear thus obviating this rejection.

Claim 93 was alleged to be indefinite in its recitation of the phrase “plant is ... chili.” The term “chili” has been deleted from amended claim 93 thus obviating this rejection.

Claim 8 has been canceled making the rejection to this claim moot.

## **V. Nonstatutory Double Patenting**

Claim 1 and dependent claims 8, 10, 42, 58-59, 62 and 68-93 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of US Patent No. 6,031,153. Claim 8 has been canceled making the rejection to this claim moot.

In view of the possibility that the scope of the claims may change in the course of prosecution, Applicants kindly request the Examiner hold this rejection in abeyance until at least one set of claims has been allowed, at which point Applicants will file a terminal disclaimer if necessary.

## **VI. Rejection under 35 U.S.C. § 101**

Claim 8 was rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 1 of prior US Patent No. 6,031,153. Claim 8 has been canceled making this rejection moot.

No new matter has been added. Therefore, Applicants respectfully request that the instant amendment be entered and receive favorable consideration. The Examiner is invited to telephone the undersigned agent if any questions or concerns arise during examination.

Respectfully submitted,



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